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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/095,478	06/10/1998	PLOWMAN GREGORY D.	235/054	9689

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/095,478	GREGORY D. ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 35-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 35-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/4/1999
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The request filed on October 9, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/095,478 is acceptable and a CPA has been established. An action on the CPA follows.

Acknowledgement is made of applicants election of the species of SEQ ID NO:5. After review and reconsideration of the claims in light of the prior art, the species election is withdrawn.

Claims 2-9, 23 and 24 have been canceled. Claims 35-37 have been added. Claims 35-37 are pending and examined on the merits.

Text of sections of Title 35, US Code not found in this action can be found in a previous action.

Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how claims 36 and 37 further limit claim 35. The specification defined the PTP05 polypeptide as a tyrosine phosphatase having a molecular weight of approximately 49kDa (page 32, lines 14-15), wherein said PTP05 is a non-receptor tyrosine phosphatase (page 32, lines 20-23). It is unclear how fragments of the proteins encoding SEQ ID NO:5, 6 and 7 would have the molecular weight of 49kDa, and it is unclear how polypeptides lacking a catalytic domain, such as those claimed in sections b, c and d of claim 37, would have tyrosine phosphatase activity. It appears that claims 36 and 37 are broader in scope than claim 35 and thus fail to further limit claim 35, or else the recitation of PTP05 polypeptide is not constrained by the limitation of having protein tyrosine phosphatase activity and the molecular weight set forth in the specification.

Claims 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

The instant claims are drawn to PTP05 polypeptides and fragments of PTP05 polypeptides. For the reasons set forth in the rejection under 112, 2nd above, the recitation of a PTP05 polypeptide is not limited by a functional attribute, such as the ability to de-phosphorylate tyrosines which have been phosphorylated by protein tyrosine kinases, nor is the recitation of a PTP05 polypeptide limited by a structural attribute such as having the complete sequence of SEQ ID NO:5, 6 or 7. Thus claims drawn to isolated, enriched or purified PTP05 polypeptides encompass a highly variant genus of polypeptides because structural and functional limitations for said genus are not present in the claims. The specification teaches that SEQ ID NO:5, 6 and 7 are members of said genus, however the description of SEQ ID NO:5, 6 and 7 are not representative of said genus, because the genus tolerates members which lack tyrosine phosphatase activity, the proteins of SEQ ID NO:5, 6 and 7 are not representative of said tyrosine-phosphatase lacking proteins.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.
Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

The specification fails to describe the PTP05 polypeptides by the test set out in Lilly or Enzo. The specification describes only full length SEQ ID NO:5, 6 and 7. Therefore, it necessarily fails to describe a "representative number" of such species of the genus which lack tyrosine phosphatase activity. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Because the claims encompass members which are fragments of the genus which inherently would lack tyrosine phosphatase activity.

Thus, the specification does not provide an adequate written description of the PTP05 polypeptides. One of skill in the art would reasonable conclude that applicant was not in possession of the genus of PTP05 polypeptides.

Claims 35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al (Journal of Biological Chemistry, 1989, Vol. 264, pp. 7747-7753).

Claim 35 is drawn to an isolated, enriched or purified PTP05 polypeptide. The specification states that PTP05 is a tyrosine phosphatase having a molecular weight of approximately 49kDa (page 32, lines 14-15), wherein said PTP05 is a non-receptor tyrosine phosphatase (page 32, lines 20-23). Claim 37 is drawn in part to the polypeptide of claim 35, comprising an amino acid sequence having (b) the full length amino acid sequence as set forth in SEQ ID NO:5 except that it lacks one or more of residues 1-187, 188-420 and 421-426 of SEQ ID NO:5. When given the broadest reasonable interpretation, claim 37 encompasses amino acid sequences lacking all of the residues of SEQ ID NO:5, because lacking "one or more" of residues 1-187, 188-420 and 421-426 can read on lacking all.

Jones et al disclose the isolated PTP-5, a protein tyrosine phosphatase having a molecular weight of 48kDa (abstract, line 15). The PTP-5 protein of Jones et al would lack residues 1-187, 188-420 and 421-426 of SEQ ID NO:5.

Claims 35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahmad et al (Journal of Clinical Investigation, 1995, Vol. 85, pp. 2806-2812).

The specific embodiment of claim 35 is recited above. Claim 37 is drawn in part to the polypeptide of claim 35, wherein said polypeptide comprises (a) full length amino acid sequences of SEQ ID NO:5, 5 or 7.

Ahmend et al disclose the preparation of human adipose tissue homogenates and the compartmentalization of the PTP enzymes from the adipose tissue into an infranate by centrifugation. The PTP05 polypeptides of SEQ ID NO:5, 6 and 7 would inherently be enriched in said infranate.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norris et al (FEBS Letters, 1997, Vol. 415, pp. 243-248).

The specific embodiments of the claims are recited above.

Norris et al teach the identification of non-receptor protein tyrosine phosphatases present in human adipose tissue (page 244, first column, lines 1-2 and Table 1, bottom section, under the heading "Intracellular PTPases". Norris et al provide reasoning challenging the hypothesis that PTP-LAR is the key regulator of the insulin receptor kinas and suggest that other PTPs are involved in insulin receptor signal transduction (page 247, second column last two paragraphs). Norris et al do not isolate enrich or purify the corresponding polypeptides encoded by the isolated DNA clones.

It would have been prima facie obvious at the time the invention was made to express the DNA clones identified in Table 1 to produce the corresponding translated polypeptides. One of skill in the art would have been motivated to do so by the suggestion of Norris et al that a different protein tyrosine phosphatase other than PTP-LAR was involved in signal transduction from the insulin receptor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
6/28/2004

Karen A. Canella

KAREN A. CANELLA PH.D
PRIMARY EXAMINER